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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HELLER, TAMMIE K	
ART UNIT	**PAPER NUMBER**
3766	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/669,154	SCHEINER, AVRAM	
	Examiner	Art Unit	
	Tammie Heller	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6,11-13 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6,11-13 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed on October 29, 2007 has been received and considered. By this amendment, claims 1 and 11 have been amended and claims 1-3, 6, 11-13, and 16 are now pending in the application.

Continued Examination Under 37 CFR 1.114

2. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Response to Arguments

3. Applicant's arguments filed October 29, 2007 have been fully considered but they are not persuasive. Regarding the rejection of the claims under 35 USC 102(e) as being anticipated by Casavant, Applicant argues that Casavant fails to disclose detecting spontaneous respiratory activity. In response to the Examiner's arguments presented in the Final Office Action of August 14, 2007, Applicant argues that the type of respiratory activity that Casavant detects is not spontaneous respiratory activity. However, Applicant fails to specify how the respiratory activity being detected by Casavant differs from spontaneous respiratory activity. Therefore, the Examiner is considering this argument moot. Further, Applicant argues that the detecting of the oxygen saturation or pressure of the blood during ventricular fibrillation is not indicative of respiratory activity, citing an article in the British Journal of Anesthesia (herein Nagdyman) as support for this assertion. The evidence presented in the Nagdyman reference indicates that during supraventricular tachycardia (SVT) without CPR the oxygen saturation of hemoglobin decreases. When CPR is administered, the oxygen saturation increases, but not to the pre-SVT level. Further, when ventricular fibrillation begins at step 4 indicated in Figure 1, the oxygen saturation increases still further. However, Applicant's arguments fail to address the effect that tachyarrhythmias may have on pressure measures. Therefore, Applicant's assertion that pressure values are not indicative of respiratory activity during ventricular fibrillation is not supported by the Applicant's arguments. Further, Applicant's evidence remains silent on the effect that ventricular fibrillation may have on oxygen saturation in the absence of a preceding SVT. Finally,

Applicant fails to disclose how Casavant would be incapable of detecting respiratory activity and respiratory arrest. It can be seen from Figure 1 of the Nagdyman reference that when respiratory arrest occurs, as it did in the patient under study, the oxygen saturation level decreases and indicates the need for CPR. Therefore, even in the presence of SVT or ventricular fibrillation, spontaneous respiratory activity and respiratory arrest will be detected based on the oxygen saturation levels.

4. Regarding the rejection of the claims under 35 USC 103(a) as being unpatentable over Scheiner in view of Min, Applicant argues that Min fails to disclose delivering diaphragmatic pacing in conjunction with delivering shock pulses for terminating ventricular fibrillation. It appears from the arguments that Applicant is arguing that Min discloses delivering cardioversion, as opposed to defibrillation, pulses to treat atrial fibrillation and ventricular tachycardias rather than ventricular fibrillation. The Examiner disagrees with this argument on both counts. Min discloses at col. 14, ln. 66-67 that the shock pulses are applied in response to the detecting of ventricular fibrillation and discloses throughout the disclosure, but specifically at col. 15, ln. 1-2 that defibrillation energy is delivered to treat the ventricular fibrillation. Therefore, Min does in fact disclose delivering shock pulses for terminating ventricular fibrillation. Further, it appears that Applicant is arguing that Min fails to disclose delivering diaphragmatic pacing when respiratory arrest is detected. The Examiner respectfully disagrees, as Min discloses at col. 6, ln. 9-22 that the presence or absence of the respiratory cycle is determined and diaphragmatic pacing is delivered, which the Examiner interprets as delivering diaphragmatic pacing when respiratory arrest is detected.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-3, 6, 11-13, and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Casavant. Regarding claims 1, 11, and 12, Casavant discloses an implantable medical device for diaphragmatic stimulation which includes ventricular sensing and shock channels (see paragraph 28, ln. 4-10 and paragraph 48, ln. 12-14), a controller 114 (see paragraph 6, ln. 1-3 and paragraph 57, ln. 1-4), and thoracic impedance and diaphragmatic pacing channels (see paragraph 16 and paragraph 48, ln. 12-14). Further, the controller of Casavant is programmed to begin charging an output capacitor of the ventricular shock channel when ventricular fibrillation is detected, deliver diaphragmatic pacing if respiratory arrest is detected and only if the output capacitor has not finished charging, and deliver a shock pulse after the output capacitor is charged, and repeat these steps (see Figure 5). At paragraph 34, Casavant discloses that stimulation is applied to the phrenic nerves in order to facilitate a more normal respiration pattern. Therefore, the Examiner takes the position that the apparatus of Casavant inherently detects respiratory activity in order to determine the rate and level of the phrenic nerve stimulation (see paragraph 73 and 74). Further, at

step 280 of Figure 7, Casavant discloses detecting the oxygen saturation or pressure of the patient. As is well known in the art, oxygen saturation and pressure are both measures that may serve as indicators of the respiratory activity of a patient. Therefore, Casavant does detect the presence of respiratory activity of a patient. Finally, Casavant discloses that a diaphragmatic pacing pulse may be delivered during a ventricular refractory period of a ventricular sense (see paragraph 36, ln. 16-19).

7. Regarding claim 2, Casavant discloses that the diaphragmatic pacing channel may also be used to deliver cardiac pacing pulses (see paragraph 48, ln. 11-12).

8. Regarding claims 3 and 13, Casavant discloses that the diaphragmatic pacing pulses may be applied at an amplitude of 20 volts (see paragraph 59, ln. 9-10), which is within the range of 10 to 30 volts.

9. Regarding claim 6, Casavant discloses that a diaphragmatic pacing pulse may be delivered during a ventricular refractory period of a ventricular sense (see paragraph 36, ln. 16-19).

10. Regarding claim 16, Casavant discloses delivering diaphragmatic pacing through a cardiac pacing channel (see Figure 1).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1-3, 6, 11-13, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheiner in view of Min et al. (U.S. Patent No. 5,836,976, cited by applicant), herein Min. Regarding claims 1, 6, and 11, Scheiner discloses a method and apparatus for diaphragmatic pacing which includes ventricular sensing and shock channels (see col. 3, ln. 59-60 and col. 4, ln. 3-7), a controller (see col. 5, ln. 63-67 and col. 6, ln. 1-3), and thoracic impedance and diaphragmatic pacing channels (see col. 5, ln. 65-67 and col. 6, ln. 1-3). Further, the controller of Scheiner is programmed to deliver a shock pulse when ventricular fibrillation is detected and deliver a diaphragmatic pacing pulse when no respiratory activity is detected (see col. 6, ln. 9-14 and 19-21). Scheiner fails to disclose charging an output capacitor when ventricular fibrillation is detected, monitoring respiratory activity while the output capacitor is charging, delivering diaphragmatic stimulation if respiratory arrest is detected and only if the output capacitor has not finished charging, and delivering a shock pulse after the output capacitor is charged. Min discloses a system which correlates the delivery of a cardioversion therapy to an optimum phase of the respiratory cycle which includes a controller which charges an output capacitor when ventricular fibrillation is detected, monitors respiratory activity while the output capacitor is charging, delivers diaphragmatic stimulation if respiratory arrest is detected and only if the output capacitor has not finished charging, and delivers a shock pulse after the output capacitor is charged (see col. 6, ln. 9-22). Further, Min discloses that the therapy is timed with respect to the cardiac cycle (read as during a refractory period) in order to avoid delivery of therapy during a vulnerable period of the cardiac cycle (see col. 6, ln. 18-22)

and the control steps taught by Min include delivering a diaphragmatic pacing pulse when both respiratory arrest and ventricular fibrillation are detected only after one or more shock pulses are unsuccessful in termination the ventricular fibrillation (see Figure 5). The controller of Min is utilized in order to affect delivery of therapy when the impedance between the stimulation electrodes is minimized (see col. 1, ln. 28-29). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to utilize the controller and control steps taught by Min, in the method and apparatus of Scheiner, in order to affect delivery of therapy when the impedance between the stimulation electrodes is minimized.

13. Regarding claim 2, Scheiner discloses that the diaphragmatic pacing channel may also be used to deliver cardiac pacing pulses (see col. 4, ln. 7-9).

14. Regarding claims 3 and 13, Scheiner discloses that the diaphragmatic pacing pulse is on the order of 0.2 to 14 volts (see col. 4, ln. 62-65), which is within the range of 10 to 30 volts.

15. Regarding claim 6, Scheiner discloses that a diaphragmatic pacing pulse may be delivered during a ventricular refractory period after a ventricular sense (see col. 9, ln. 29-30).

16. Regarding claim 12, Scheiner discloses that the diaphragmatic pacing is delivered as pacing pulses to the phrenic nerve (see col. 3, ln. 43).

17. Regarding claim 16, Scheiner discloses delivering diaphragmatic pacing through a cardiac pacing channel (see Figures 1A and 1B).

Conclusion

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tammie Heller whose telephone number is 571-272-1986. The examiner can normally be reached on Monday through Friday from 7am until 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tammie K. Heller
Patent Examiner
Art Unit 3766

CARL LAYNO
PRIMARY EXAMINER